

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0522069	(X3) Date Survey Completed 04/27/2022
Name of Provider or Supplier North Idaho Urology	Street Address, City, State 980 W Ironwood Dr #104, Coeur D'Alene, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of training and competency assessment records, laboratory procedures, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with the general supervisor on 4/27/2022, the laboratory failed to establish and follow written policies and procedures to assess employee competency. The findings include: 1. The CMS 209 identifies one (1) testing personnel performing moderate complexity urine microscopic and post vasectomy testing. 2. A review of laboratory procedures identified that the laboratory failed to establish policies or procedures to assess employee initial, semiannual and annual competency. 3. A review of training and competency assessment records identified that the laboratory failed to have competency assessments for 2021 for one (1) of one (1) testing personnel performing urine microscopic and post vasectomy testing. 4. An interview with the general supervisor on 4/27/2022 at 2:18 pm, confirmed that there was no documented 2021 competency assessments for one (1) of one (1) testing personnel performing urine microscopic and post vasectomy testing. 5. The laboratory reports performing 6600 urine microscopic tests and 80 post vasectomy tests annually. 6. This is a repeat deficiency from the survey performed on 1/5/2021.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
Based on a review of laboratory's proficiency test results and an interview with the general supervisor on 4/27/22, the laboratory failed to verify the accuracy of urine microscopic testing twice annually. The findings include: 1. A review of the laboratory's proficiency test results identified that the laboratory failed to perform biannual verification of testing performance for urine microscopic testing for 2021. 2. An interview with the general supervisor on 4/27/2022 at 2:34 pm confirmed that biannual verification for urine microscopic testing for 2021 was not performed. 3. The laboratory reports performing 6600 urine microscopic tests annually.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of patient test reports and an interview with the general supervisor on 4/27/2022, the laboratory failed to include normal values on final test reports. The findings include: 1. A review of patient test reports identified that the laboratory failed to include normal values for urinalysis and post vasectomy testing on patient final test reports. 2. An interview with the general supervisor on 4/27/2022 at 4:30 confirmed that urinalysis and post vasectomy test reports failed to include normal values. 3. The laboratory reports performing 6600 urine microscopic tests and 80 post vasectomy tests annually.